NDA 20-802/S-004

SEP 7 2000

Bristol-Myers Products
Attention: Steven J. Knapp, R.Ph.
1350 Liberty Avenue
Hillside, NJ 07207

Dear Mr. Knapp:

Please refer to your supplemental new drug application dated May 10, 1999, received May 11, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Excedrin Migraine (acetaminophen 250 mg, aspirin 250 mg, caffeine 65 mg) Tablets, Caplets, and Geltabs.

This "Changes Being Effected" supplemental new drug application provides for revised labeling that: presents abbreviated labeling for the inner label of the smaller package sizes in a larger type size; defines the term "caplet" as a "capsule-shaped tablet;" eliminates the word "New;" and presents both words which constitute the product name, Excedrin Migraine in type size that is closer m size.

We have completed the review of this supplemental new drug application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling submitted on May 10, 1999. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

Please submit 20 paper copies of the final printed labeling (FPL) as soon as it is available, in no case more than 30 days after it is printed. Please mount individually ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled ProvidingRegulatory Submissions in Electronic Format NDAs (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplemental NDA 20-802/S-004." Approval of this submission by FDA is not required before the labeling is used.

We request that the following revisions in the labeling for this drug product be implemented within 180 days or at the next printing, whichever comes first:

1. For the outer carton/bottle label, the letter "A" in "Alert" should appear in lower case.

2. For the outer carton, the letter "W" in "Alcohol Warning" should appear in lower case.

3. On the outer carton label, under the "Stop **using this product and see a doctor it"** subheader, a period should be placed at the end of the first bulleted statement, "an allergic reaction occurs. Seek medical help right away."

4. For the outer carton/bottle label, the storage statement should read "store at 20- 25°C (68 - 77°F)."

5. The "caffeine warning" header should be added in bold type to read:

   "**Caffeine warning**: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heart beat."

6. Add the lot and control number and the expiration date on the immediate container.

7. The subheaders "**Do not use**" and "**Stop use and ask a doctor if**' should appear in bold type on the immediate container.

Furthermore, we note that the labeling was not submitted in Drug Facts format consistent with the requirements of the March 17, 1999 FEDERAL REGISTER document "Over-the-Counter Human Drugs; Labeling Requirements; Final Rule" (64 FR 13254) (OTC labeling final rule), which has been incorporated into the regulations at 21 CFR 201.66. We remind you that the labeling of your product must be revised to reflect the Drug Facts format within the timeframes specified in the OTC labeling final rule.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MED WATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857.

We remind you that you must comply with the requirements for an approved NDA set forth under2l CFR 3l4.80 and 3l4.81.